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Anticipated Regret and Organ Donor Registration: a randomised controlled trial

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Running Header: Anticipated Regret and Organ Donation

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Abstract

Objective: To test whether simply asking people to rate the extent to which they anticipate feeling regret for not registering as an organ donor after death increases subsequent verified organ donor registration. **Methods:** 14,509 members of the general public (both registered and non-registered donors) were randomly allocated to 1 of 4 arms, each receiving different questionnaires. The no-questionnaire control (NQC) arm received a survey measuring demographics and whether or not they were registered organ donors. The questionnaire control (QC) arm completed the NQC questions plus questions regarding affective attitudes and intention to register as an organ donor. The theory of planned behaviour (TPB) questionnaire arm received the QC questionnaire, plus additional items measuring TPB variables. The anticipated regret (AR) arm received the TPB questionnaire, plus two additional items measuring anticipated regret. The main outcome measures were number of non-donor participants who subsequently registered six months later, as verified by the UK national transplant register. **Results:** Intention-to-treat (ITT) analysis in non-registered donors (N = 9,139) revealed the NQC arm were more likely to register as an organ donor (6.39%) compared to the AR (4.51%) arm. **Conclusions:** A brief anticipated regret intervention led to a decrease in registration. A potential reason is discussed in terms of questionnaire item content “priming” negative perceptions of organ donation. This is a methodological concern that needs to be addressed in studies that use similar interventions. Current controlled trials: www.controlled-trials.com number: ISRCTN922048897.

Introduction

There is an insufficient supply of donor organs to meet the demand for organ transplantations worldwide. In June 2015 in the US, over 123,000 residents were on the waiting list for a solid organ transplant, with 21 patients dying per day before receiving a transplant (<http://www.organdonor.gov/>). In the UK, over 90% of the general public approves of organ donation but only 32% have registered (<http://www.organdonation.nhs.uk>). There is therefore an urgent need to identify and overcome the barriers to registration.

Outside of large scale policy interventions to influence organ donation (e.g., opt-in versus opt-out consent: Shepherd, O'Carroll, & Ferguson, 2014), recent work has suggested that decision making regarding organ donor registration may not be primarily due to cognitive evaluations of evidence, but may be more influenced by emotional/visceral affective beliefs and attitudes (Morgan, Stephenson, Harrison, Afifi, & Long, 2008). Examples of these affective attitudes include the “ick factor”, a basic disgust reaction to the idea of organ donation, and the “jinx factor”, the superstitious belief that registration will in some way lead to harm or death for the registrant. Morgan et al. (2008) found that in the US, these types of factors were, compared to traditional, rational-cognitive components of the Theory of Planned Behavior (TPB), (e.g. attitude and subjective norm), the best predictors of whether people had registered as organ donors. O'Carroll, Foster, McGeechan, Sandford, and Ferguson (2011b) replicated this finding in the UK.

Anticipated regret (AR)

The above findings suggest that emotional factors are a potentially useful avenue to pursue for interventions to increase organ donor registration. This paper focuses on one such emotional factor: anticipated regret. Regret is an aversive emotion that people are strongly motivated to avoid (Zeelenberg, 1999). It is also possible to anticipate regret and thus avoid actually experiencing this unpleasant emotion in the future (Bell, 1982; Loomes & Sugden,

1982; Simonson, 1992; Zeelenberg & Pieters, 2007). It has been shown that over and above the traditional components of the TPB, AR adds significantly to the prediction of intentions to use condoms, avoid engaging in casual sex, reduce alcohol, junk food, and soft drink consumption, and, also, commit fewer driving violations, protect one's health, initiate exercise, and reduce smoking initiation (Sandberg & Conner, 2009; for reviews, see Manstead, 2000; Sandberg & Conner, 2008). As a result, AR should motivate people to undertake an action in order to avoid harmful future emotional consequences. Indeed, AR interventions are likely to improve self-reported health behaviors (e.g., Abraham & Sheeran, 2003; Richard, Van Der Pligt, & De Vries, 1996; Sandberg & Conner, 2009) as well as objective behaviors such as attending for cervical screening (Sandberg & Conner, 2009). Of more direct relevance to organ donation, Godin, Sheeran, Conner, & Germain (2008) randomly assigned participants to an experimental arm receiving a postal questionnaire measuring cognitions about blood donation (including AR items) or a control arm that did not receive a questionnaire. Compared to controls, the mean frequency of registrations at blood drives among participants in the experimental group was 8.6% greater at 6 months, and was 6.4% greater at 12 months. Godin et al. (2010) conducted a further RCT which attempted to increase blood donation in novice donors. They found that: (a) questionnaire completion led to a significant increase in donations, and (b) simple "if-then" planning, specifying how, where, and when donation would occur (implementation intentions), led to a 12% increase in donations. Manipulating AR in this study did not augment the intervention effect. However, this study (unlike others) measured AR with isolated questions rather than embedded within a questionnaire containing other items. The authors speculated that this may have been too blatant. Participants may have interpreted the obvious AR questions as an unsubtle emotional appeal and may have refused to modify their behavioural intentions accordingly. This suggests the need to embed AR items.

AR and Organ Donations

Thus, it is a plausible expectation that manipulating exposure to AR should result in increased levels of organ donation. This is strengthened by a recent paper (O'Carroll et al., 2011b) which tested a simple AR intervention on intentions to register as an organ donor. Non-registered donors were randomly allocated to a questionnaire control (QC) or AR arm. The QC group completed a modified version of the affective attitudes questionnaire (Morgan et al., 2008) assessing ick and jinx factors. Those allocated to the AR arm completed the same questionnaire plus two additional questions measuring anticipated regret. The mean intention to become an organ donor for those exposed to the AR arm was significantly higher than in the QC arm. Importantly, this research found that the effect of the AR intervention on intentions was mediated by affective attitudes; specifically, perceived benefit. A further replication was also conducted using a web-based recruitment and assignment process (O'Carroll, Dryden, Hamilton-Barclay, & Ferguson, 2011a). Adults who had not registered as organ donors were allocated to one of three arms. The first arm (QC) completed affective attitudes questionnaire, measuring ick, jinx etc.). The second arm (Theory of Planned Behaviour or TPB) completed the same questions as the QC arm plus additional items measuring theory of planned behaviour constructs (attitude, subjective norm, and perceived control). Finally, the AR arm completed the same questions as the TPB arm plus 2 additional AR questions. All participants were followed up 1 month later and 13% of the QC group, 7.9% of the TPB group, and 21.8% of the AR group reported that they had registered as an organ donor since completing their questionnaire. While these are promising findings, they all involve self-reported organ donor registration or intentions. The critical test is whether or not this simple AR intervention leads to a significant increase in verified registrations to become an organ donor after death. Therefore, the study reported in this paper tests whether a

large scale, simple AR intervention leads to a significant increase in verified organ donor registrations.

Previous research has suggested that completing a questionnaire may create a potential reactivity effect (Sandberg & Conner, 2009). Indeed, asking people about organ donation may increase registration. Therefore, we enhanced previous research by including a no questionnaire control arm (NQC). This arm did not rate their thoughts and beliefs towards organ donation. As such, they served as an additional control condition. We hypothesised that simply asking people to think about and rate their anticipated regret should result in greater rates of verified organ donor registration in the AR arm than the NQC, QC, and TPB arms.

Method

The full study protocol has been published (O'Carroll et al., 2012) and the study is registered - International Standard Randomized Controlled Trial Number (ISRCTN) 92204897.

Participants

A sample of 14,509 participants was randomly selected from a list containing 1.2 million members of the adult Scottish general public in April 2012. Each participant received a questionnaire pack which contained a cover letter about the study, a questionnaire, an organ donor registration form, and a stamped addressed envelope. In all arms, the cover letter informed participants that this study was assessing their attitudes towards organ donation and that their permission for the organisation responsible for maintaining the organ donor register (UK NHS Blood and Transplant or NHSBT) to search the UK organ donor register 6 months later was being sought. People who did not want to be part of this research were asked to opt out. In order to maximise the response rate, key recommendations from a recent Cochrane Review were implemented (Edwards et al., 2009), including personalising the cover letter to each individual, the use of hand-written signatures in blue ink, emphasising confidentiality and anonymity, etc. In this study, 2558 of the 14,509 participants returned a questionnaire,

resulting in an overall response rate of 17.63%. However, this response rate rose to 19.72% once the ineligible participants were excluded (see next section).

Eligibility and exclusion criteria

To be eligible to take part in this study, participants had to be 18 years or older and live in Scotland. This eligibility was determined prior to the questionnaire packs being posted by the market research company (Perspektiv: <http://www.perspektiv.co.uk/>) that coordinated the distribution of the survey on behalf of the research team. While the survey sampling protocol was clearly defined, it was possible that there were some protocol errors. For example, the addresses of some participants may have been incorrect (e.g., they may have moved). Similarly, although the mortality checks were as up to date as possible, some participants may have died prior to the survey being posted. Therefore, we excluded people after the questionnaire packs had been posted. We excluded people when the name or address of the individual was incorrect, if we were informed that the person was either below 18 years, deceased or did not live in Scotland. Finally, anyone who was registered as an organ donor prior to the questionnaire packs being posted (according to NHSBT) was ineligible. This was determined using the search of the organ donor register that occurred 6 months after the questionnaire packs were posted. Thus, this exclusion took place after the packs were sent out as, due to confidentiality and ethical requirements, the market research company who posted the questionnaires were not able to access the organ donor register to check registration status.

Ethical approval

Approval was obtained from UK NHS Blood and Transplant who are responsible for the UK organ donor register. Full UK National Health Service IRAS ethical approval (11/SS/0093) was achieved. Due to the sensitive nature of this topic, approval was limited to

one mailing/contact. Finally, the study was approved by the Ethics Committee of the Department of Psychology at the University of Stirling, where the study was conducted.

Design and Materials

Although demographics were collected on the questionnaires, the age and gender data from the market research company's sources was used in the analysis so that the participant was not required to complete the questionnaire to obtain this data. The participant's postcode was used to estimate their socio-economic status (SES), using the Scottish Index of Multiple Deprivation (SIMD; <http://www.scotland.gov.uk/Topics/Statistics/SIMD>). This tool is used by the Scottish Government to determine areas of deprivation in Scotland. SIMD uses data from different domains (e.g., income, employment, health, education) to calculate a score indicating the level of deprivation in an area. In this study, we used the decile indicator of SES from SIMD, with 1 indicating the most deprived areas in Scotland and 10 the least deprived areas in Scotland. We did not measure education level, but SES is a good proxy for education.

Although the participant's organ donor status was requested on the questionnaire, the information obtained from NHSBT on donor status was used to ensure that the analysis was based on the most accurate measure (for details, see below).

This was a randomised controlled trial. Participants were randomly assigned to one of the four experimental arms of the study: no questionnaire control (NQC), questionnaire control (QC), theory of planned behaviour questionnaire (TPB), and anticipated regret (AR). Simple randomisation was used to allocate people into each arm (Schulz & Grimes, 2002) in a 1:1:1:1 ratio. Households were identified via a list broker which was coordinated by the market research company, Perspektiv, and only one person per household was selected to be invited to take part to avoid cross-contamination of responses. The invitation to take part was addressed personally to that individual and they were instructed that only they and no-one

else in their household should complete it. The randomization sequence, participant enrolment and the assignment of participants to experimental conditions was done by the market research company. This company is experienced in this type of work and has worked on a number of published projects of this nature (Ferguson, Lawrence, Bibby, Leaviss & Moghaddam, 2006; Ferguson, Prowse, Townsend, Spence, van Hilten & Lowe 2008; Ferguson, Spence, Townsend, Prowse, Palmer, Fleming & Van Hilten, 2009). Participants were blind to the experimental arm.

Questionnaires

NQC Participants in the NQC arm completed a short survey measuring demographic information (gender, date-of-birth, occupation, and postcode for socio-economic status estimation). These participants also completed items measuring whether they were a registered organ donor, knew anyone who had received an organ transplant, knew anyone who had donated an organ, knew anyone who needed an organ, whether they had donated an organ, and whether they had donated blood (yes versus no for each of these items), and if they had donated blood, how many times they had done this in their lifetime. Participants in this arm did not complete any other items. Questionnaires in the remaining arms were the same as the NQC plus an additional 27 items.

QC The questionnaire for participants in the QC arm contained the same items as the NQC arm, plus 16 additional items measuring their non-cognitive affective attitudes towards donation using the scales developed by Morgan et al., (2008) (see also O'Carroll et al., 2011a) to assess bodily integrity, medical mistrust, the 'ick factor', jinx, and perceived benefits. All items were rated on a 7-point Likert scale (1 = strongly disagree, 7 = strongly agree). Bodily integrity was measured with two items (e.g., 'Removing organs from the body just isn't right'), $r = .75$, $p < .001$ for all people who were non-donors (according to NHSBT) prior to returning the questionnaire (including those in TPB and AR arms). There were four medical

mistrust items (e.g., ‘If I sign an organ donor card, doctors might not try so hard to save my life’), $\alpha = .73$. The ‘ick factor’ was measured using three items (e.g., ‘The idea of organ donation is somewhat disgusting’), $\alpha = .74$. Jinx was measured with three items (e.g., ‘The surest way to bring about my own death is to make plans for it like signing an organ donor card’), $\alpha = .63$. There were four perceived benefit items (e.g., ‘Organ donors are heroic because they save lives’), $\alpha = .67$.

Participants in the QC arm also rated their intention to register as an organ donor on a two-item scale (e.g., ‘I will definitely register as an organ donor in the next few months’, 1 = strongly disagree, 7 = strongly agree), $r = .86$, $p < .001$ for intention items (includes participants in QC, TPB, and AR arms). Moreover, participants completed 9 non-reactive “filler” items (e.g., ‘Organ donation is a private matter’) to ensure that the number of items in the QC arm was identical to that of the TPB and AR arms.

TPB The TPB questionnaire contained the same 16 affective and intention items as the QC questionnaire, plus 7 additional items measuring attitude, subjective norm, and perceived control. Attitude was measured with two items (e.g., ‘I support the idea of organ donation for transplantation purposes’, 1 = strongly disagree, 7 = strongly agree), $r = .80$, $p < .001$ (includes TPB and AR arm). Subjective norm was measured using two items (e.g., ‘Most people who are important to me think I should register as an organ donor in the next few months’, 1 = strongly disagree, 7 = strongly agree) $r = .48$, $p < .001$. Perceived control was measured with three items (e.g., ‘How much control do you have over registering as an organ donor in the next few months’, 1 = no control, 7 = complete control) $\alpha = .61$. Participants also answered two filler items to ensure that the total number of items was identical to that of the AR arm.

AR The questionnaire for the AR arm contained the same affective, intention and TPB items as the TPB arm, plus two additional items measuring the extent to which the participant

anticipated regret for not registered as an organ donor (“If I did not register as an organ donor in the next few months, I would later wish I had”, and “If I did not register as an organ donor in the next few months I would feel regret” (1 = strongly disagree, 7 = strongly agree), $r = .62$, $p < .001$.

Donor Registration Participants in all four arms were informed that they could register as an organ donor by visiting the UK NHSBT website (the website address was given to the participants), by completing and returning the enclosed organ donor registration form to the research team in the stamped addressed envelope provided, by calling NHSBT (telephone number was provided), or by texting NHSBT (text instructions were provided). Six months after the questionnaires were posted (October 2012), NHSBT performed a confidential (i.e. completely independently of the researchers) search of the UK organ donor register to determine whether or not the participant had registered as an organ donor. This was the main outcome measure. Importantly, the NHSBT staff who searched the register were blind to the experimental arm to which the participant was allocated.

Power Analysis

A pilot study (O’Carroll et al., 2011a) found that 13% of the control group, 7.9% of the TBP group, and 21.8% of the AR group subsequently registered as an organ donor. Based on this, it was calculated that, in order to obtain a significant effect with an alpha of .05 and with power of .80, an N of 291 per group was required to find a difference between the QC and the AR arms. An N of 102 per group was needed to find differences between the TPB and AR arms. Finally, an N of 565 was needed to find a difference between the QC and TPB arms. Therefore, an N of 565 was needed to find the differences between the arms. However, it was necessary to adjust the sample to account for the fact that 32% of the Scottish population were already registered organ donors, and that response rates for this type of research are typically between 23%-37% (Edwards et al., 2009). Based on the lower response

rate (23%), and the fact that 32% of people are already registered, it was calculated that a sample of 3,630 would be more than sufficient to find a significant effect.

Statistical Analysis

Data were analysed using both intention-to-treat (ITT) and per protocol (PP) analyses (Sussman & Hayward, 2010). For the eligible participants (N = 9,208, see below), there were no missing data for the conditions, age, and compliance variables. There was a small amount of missing data for the gender (0.71%) and the SES variable (0.04%). Because of the small amount of missing data, listwise deletion was used throughout the analyses. Subsequent analysis revealed that the results were the same when multiple imputation was used.

Results

Exclusions

There were 729 participants (5%) who were ineligible to take part in the survey (see Figure 1). An additional 806 participants were withdrawn from the sample because they opted-out. Because this intervention was not relevant to people who were registered donors prior to receiving the intervention (as determined by NHSBT), they were also excluded.

Randomization occurred prior to the exclusion of the participants (for baseline demographics, see Table 1, Panel A). Therefore, it was important to test whether or not the exclusion of participants biased the randomization. First, a test was conducted to see whether people's organ donor status prior to the questionnaire being posted varied as a function of the study arm. This analysis was performed on all participants who were eligible to take part in the study (N = 12,974). There was no significant association between arm allocation and the participant's organ donor status prior to receiving the intervention ($\chi^2(3) = 2.94$, $p = .401$), implying that the number of registered and non-registered donors did not systematically vary across the four arms. Thus removing the registered donors should leave a sample whereby non-registered donors are randomly allocated across arms. Next, we assessed whether the

demographics of the eligible non-donors ($n = 9,208$ prior to listwise deletion) differed between the 4 arms. There were no significant differences between the four arms with regards to age, gender, or socio-economic status for decile (see Table 1, Panel A).

Compliance (questionnaire return and exposure to active ingredients) with the Protocol

In this area of work, outcomes are also usually analysed for those who returned questionnaires¹ as this may reflect people who are also likely to be compliant to the target behaviour (e.g., O'Carroll, Chambers, Brownlee, Libby, & Steele, 2015). However, this does not take into account whether or not they have completed the key items (the active ingredients in these studies) in the questionnaire. As such, we do not know if they are compliant in the sense of being exposed to the intervention's active ingredients, rather than just compliant at returning questionnaires. For example, a participant in the AR arm may have returned the questionnaire but not completed the two anticipated regret items. As such, they are a compliant "questionnaire-returner" but may have not been exposed to the key active ingredients of the AR arm in the trial. Therefore, the index of compliance that was used was defined as having completed all active (or corresponding filler) items (i.e. 11 in total). Thus, in the QC arm participants had to complete the 2 intention and 9 filler items to be regarded as compliant. In the TPB arm participants had to complete the 2 intention, 2 attitude, 2 subjective norm, 3 perceived control, and 2 filler items to be compliant. In the AR arm the participant had to complete the 9 intention, attitude, subjective norm, and perceived control items, plus the two anticipated regret items. However, because there was no active ingredient in the NQC arm, all participants who returned the questionnaire in this group were regarded as compliant.

¹ Additional analysis on predictors of questionnaire return is presented in the Supplemental Material

Next, any differences between participants who did and did not comply with the protocol were assessed. In line with ethical guidelines, this analysis was not conducted on anyone who withdrew for the study or was ineligible to participate (leaving a final N of 9,208 prior to listwise deletion). There was a significant association between arm and compliance (see Table 1, Panel B). There was also a significant association between gender and compliance, with women being more likely to comply than men (females: $n = 627/5140$ (12.2%) compliant vs males: $n = 342/4003$ (8.5%); $\chi^2(1) = 31.73$, $p < .001$). People who complied were older than those who did not ($M = 45.44$, $SD = 10.63$ versus $M = 40.49$, $SD = 11.81$; $t(1279.43) = 13.60$, $p < .001$, Glass's $\Delta = 0.42$). Finally, people who complied with the protocol were of higher SES ($M = 5.78$, $SD = 2.69$ versus $M = 4.98$, $SD = 2.79$; $t(9202) = 8.47$, $p < .001$, Cohen's $d = 0.29$). A multivariate logistic regression examined how these variables uniquely predict compliance. This analysis found that compliance was lower in the QC ($B = -0.19$, $p = .047$, $OR = 0.83$), TPB ($B = -0.27$, $p = .004$, $OR = 0.76$) and AR arms ($B = -0.49$, $p < .001$, $OR = 0.61$), relative to the NQC arm. This analysis also found that compliance was higher in women than men ($B = 0.40$, $p < .001$, $OR = 1.49$), and that it was positively associated with both age ($B = 0.04$, $p < .001$, $OR = 1.04$) and SES ($B = 0.09$, $p < .001$, $OR = 1.09$).

Organ donor registration

A total of 5.40% ($N = 497$) of the 9,208 participants who were not registered prior to receiving the questionnaire subsequently registered as a verified organ donor. For the participants who complied with the intervention, the percentage that registered was much higher (compliers: $n = 382/977$ (39.10%) versus non-compliers $n = 115/8231$ (1.40%); $\chi^2(1) = 2431.20$, $p < .001$), indicating a significant association between protocol compliance and registering as an organ donor. There was a small, significant overall effect of arm on organ

donor registration (see Table 1, Panel C). Women were more likely to register than men (females: 321/5140 (6.25%) versus males: 173/4003 (4.32%), $\chi^2(1) = 16.29$, $p < .001$).

ITT Analyses

The primary analysis for this study ($N = 9,139$) was a logistic regression model to determine whether the proportion of respondents who registered as an organ donor after receiving the intervention varied between arms. In these analyses the predictor variables were arm (with NQC as the reference R category), age, gender, and SES, (Table 2, columns 2 and 3). The covariates (age, gender, and SES) were entered into the model in the first step, and arm was entered into the model in the second step.

The Nagelkerke pseudo- R^2 (Nagelkerke, 1991) for the first step was 0.03 ($p < .001$). This step demonstrated that females were more likely to register than males, and that age and SES positively predicted registration (Table 2, Step 1, column 2). The Nagelkerke pseudo- R^2 for the 2nd step was 0.03 ($p < .001$). Importantly, including arm into the model significantly increased its predictive power ($\Delta\chi^2(3) = 8.29$, $p = .040$ for the step). In Step 2, the covariates remained significant predictors of organ donor registration (Table 2, Step 2, column 3). People were less likely to register in the AR than the NQC arm (Table 2, Step 2, column 3). Although registration was lower in the QC and TPB arms than the NQC arm (Table 1, Panel C), these differences were not significant.

PP Analyses

The analysis was restricted to the participants who had complied i.e., returned the questionnaire and completed the items (see Table 2, columns 5 and 6). Although 977 participants had complied, this sample was reduced to 961 after listwise deletion. This was due to missing data on the covariates. Similar to the whole non-donor sample, for the compliant participants, the number of donors in the NQC ($n = 130$, 43.33% of arm) was greater than the QC ($n = 87$, 35.37%), TPB ($n = 95$, 39.58%), and AR ($n = 70$, 36.65%) arms.

However, the association between arm and organ donor registration was non-significant ($\chi^2(3) = 4.20$, $p = .240$). Moreover, donor rates were similar between males ($n = 135$, 39.47% of males) and females ($n = 245$, 39.07% of females).

We measured a variety of covariates that may predict registration. These included knowing a recipient of an organ transplant (know recipient), knowing a donor (know donor), knowing someone who needs an organ (know need), and whether or not they have donated blood (donated blood). These covariates were not included in the ITT analysis because most participants did not return the questionnaire, but were entered into Step 1 of the PP model alongside the covariates included in the ITT analysis (gender, age, and SES). Treatment arm was added at the 2nd step.

In Step 1, the Nagelkerke pseudo- R^2 was 0.01 ($p = .598$). Although SES negatively predicted organ donor registration, this relationship was only marginally significant (Table 2, Step 1, column 5). In Step 2, the Nagelkerke pseudo- R was 0.01 ($p = .422$). Although adding arm into the model increased its predictive power, this was not significant ($\Delta\chi^2(3) = 4.70$, $p = .195$). Despite this non-significant result, it is worth noting that organ donor registration rates were significantly lower in the QC than the NQC arm (Table 2, Step 2, column 6).

Post hoc power analyses were conducted to determine the extent to which power varied between the ITT and PP analyses (Table 2, columns 4 and 7). In line with the analyses, power was lower in the PP than ITT analysis. This suggests that these differences may in part be due to power differences between the analyses.

Anticipated Regret, Intention and Behaviour

A further examination of anticipated regret aimed to determine why the apparent AR effects in the ITT analysis were contrary to previous findings. First, we assessed whether or not having high scores on the measured anticipated regret variable (i.e., the two items in the AR arm) promotes organ donor registration. This analysis could only be undertaken on the

compliant participants in the AR arm because the anticipated regret items needed to be completed. We conducted a median split ($Mdn = 4$) on this variable to assess the effects of low versus high levels of anticipated regret on organ donor registration intention and behaviour. Given that the mean level of anticipated regret was 3.96 ($SD = 1.68$), participants with the median score (4) were placed in the high anticipated regret group. As a result, there were 73 participants in the low regret group and 118 in the high regret group. People's intention to register as an organ donor was significantly greater in the high ($M = 5.50$, $SD = 1.35$) compared to the low regret ($M = 2.68$, $SD = 1.76$; $F(1, 189) = 156.17$, $p < .001$, $\eta_p^2 = .45$) groups. This difference remained significant after controlling for the covariates in the PP analysis (for list of variables see below; $F(1, 179) = 148.27$, $p < .001$, $\eta_p^2 = .45$). Registration rates were significantly greater in the high versus low anticipated regret group both before ($B = 1.73$, $n = 191$, $p < .001$, $OR = 5.64$), and after controlling for the covariates in the PP analysis ($B = 2.00$, $n = 188$, $p < .001$, $OR = 7.40$), with 59 participants (50.00%) registered as an organ donor in the high regret group, and 11 participants (15.07%) in the low regret group. These results demonstrate a strong association between higher self-reported anticipated regret and increased organ donor intentions and registrations.

Return Rate and Organ Donor Registration

As mentioned above, organ donor registration was lower in the AR arm than the NQC, QC, and TPB arms. We also observed that participants were less likely to return the questionnaire in the AR arm ($n = 255$, 11.05%) than the NQC ($n = 300$, 12.88%), QC ($n = 310$, 13.74%), and TPB arms ($n = 300$, 12.97%; $\chi^2(3) = 8.08$, $p = .044$; for more details, see supplementary information). Based on this, it could be argued that the lower organ donor registration rates in the AR arm were due to these participants being less likely to return the questionnaire. To test this, we re-ran the ITT analysis with returning the questionnaire added as an additional covariate. In this analysis the Nagelkerke pseudo-R was 0.48 ($p < .001$).

After controlling for returning the questionnaire, organ donor registration was not predicted by age ($B < 0.01$, $p = .958$, $OR = 1.00$), gender ($B = 0.01$, $p = .962$, $OR = 1.01$), or SES ($B = -0.03$, $p = .187$, $OR = 0.97$). Returning the questionnaire was positively associated with organ donor registration ($B = 4.45$, $p < .001$, $OR = 85.19$). Importantly, even after controlling for returning the questionnaire, registration rates were lower in the AR arm than the NQC arm ($B = -0.35$, $p = .025$, $OR = 0.70$). After controlling for returning the questionnaire, registration rates for the QC arm were also lower than the NQC arm ($B = -0.40$, $p = .009$, $OR = 0.67$). In contrast, there was still not a significant difference between the NQC and TPB arms ($B = -0.28$, $p = .062$, $OR = 0.75$). These results reflect the fact that the lower registration rates in the AR arm was not due to these participants being less likely to return the questionnaire.

Discussion

Contrary to expectations and previous studies (O'Carroll et al., 2011a; O'Carroll et al., 2011b), the AR intervention did not increase organ donor registration. Instead, the ITT analysis found that overall organ donor registration was lower in the AR arm than the control arm.

The main difference between the active arms and the NCQ was that the NQC participants did not complete the items assessing affective attitudes towards organ donation (e.g., jinx, medical distrust) nor any other negative items. Asking people to complete these items exposed them to rating their feelings concerning emotional barriers to organ donor registration (i.e., ick factor). This exposure may have reduced the likelihood of participants registering as an organ donor. This may be an example of a negative contextual cuing effect that can result from question exposure, which has been reported before in the blood donation literature (Farrell, Ferguson, James, & Lowe, 2002). In addition, those in the AR condition completed two AR items that increased the negative item content of this arm relative to the

TPB and QC arms. Thus, it may be that exposure to negative items results in lower registration rates.

We did observe that those who reported higher levels of AR were up to 7 times more likely to register as a donor. Thus, it should be stressed that the findings do not indicate that AR interventions are likely to be unsuccessful. Indeed, successfully increasing AR should increase donor registration, but this large-scale questionnaire-based intervention was not effective overall. Thus, while individual differences in expressed AR are an important determinant of donor registration, this may not be seen at a population level when embedded with a large number of negative items. That is, at an ITT level of analysis, the overall epidemiological effect is that more negative content is problematic and may lead to reduced registration. This highlights the need to consider the theoretical and practical effects at the population level and individual level as distinct (Ferguson, 2013).

Three key practical recommendations arise from this work. First, researchers need to clearly define what they mean by compliance. If there are questions embedded in the questionnaire that are the ‘active’ ingredient of the intervention, then compliance has to include completing these. Participants who do not complete these items have not complied, and this may obscure the true nature of any effects. Second, researchers should report the number of active ingredient questions relative to the number of questions asked. If there are 2 out of 20 active ingredient question compared to 2 out of 40, the effect should be weaker in the latter case. Finally, researchers should report the relative valence of their questions. If there is a high proportion of negative valenced questions in an intervention that is supposed to be promoting a behaviour, this may negate any effects. Indeed there is a large literature on item and question context effects like this (see Farrell et al., 2002).

This study used random sampling to create a large, representative sample of participants from the Scottish general public, thereby resulting in high levels of external

validity and generalizability. However, one potential limitation is that compliance was predicted by age, gender, and SES, thereby causing some bias in the compliant sample. Although these factors did not vary between the arms, the compliant sample was more likely to be female, older, and of higher SES than the original sample obtained through random sampling. However, these were controlled for in the analyses. Moreover, there may be other differences between the original and compliant sample that were not measured. Secondly, the low response rate may have introduced sampling bias. We also acknowledge that our PP analyses may be underpowered. The combination of this with the restricted sample may explain why our covariates predicted registration in the ITT analysis but not the PP analysis. However, both ITT and PP analyses found higher rates of registration in the NQC arm, suggesting that this is a robust effect.

Conclusions

This study found that a simple AR intervention did not increase organ donor registration. Instead, participants in the AR arm were less likely to register as an organ donor than those in the no questionnaire control arm. This may have been because people in this arm were also induced to think about reasons to not donate (i.e., the "ick factor"), whereas control participants may not have had such reasons readily available to them. Researchers should consider the potential influence of each item in a questionnaire to ensure that the inclusion of affective attitude items does not reduce the effectiveness of their proposed intervention.

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Table 1. (Panel A) Association of arm with age, gender, and SES; (Panel B) Association of arm with compliance; (Panel C) Association of arm with organ donor registration (n = 9,208)

Panel A					
	Arm				Significance
	NQC	QC	TPB	AR	
n	2330	2257	2313	2308	
Age M (SD)	41.28 (11.70)	40.81 (11.65)	41.32 (11.95)	40.65 (11.83)	$F(3, 9204) = 1.86, p = .134, \eta_p^2 < .01$
Gender n males (%)	1012 (43.79)	998 (44.53)	999 (43.47)	994 (43.35)	$\chi^2(3) = 0.78, p = .855$
SES M (SD)	5.02 (2.81)	5.11 (2.82)	5.04 (2.79)	5.08 (2.76)	$F(3, 9200) = 0.46, p = .709, \eta_p^2 < .01$
Panel B					
Non-compliant n (%)	2030 (87.12)	2011 (89.10)	2073 (89.62)	2117 (91.72)	$\chi^2(3) = 26.20, p < .001$
Compliant n (%)	300 (12.88) ^a	246 (10.90) ^{a,b}	240 (10.38) ^{b,c}	191 (8.28) ^c	NCQ>TPB & AR, QC>AR
Panel C					
Non-donors n (%)	2181 (93.61)	2138 (94.73)	2188 (94.60)	2204 (95.49)	$\chi^2(3) = 8.20, p = .042$
Donors n (%)	149 (6.39) ^a	119 (5.27) ^{a,b}	125 (5.40) ^{a,b}	104 (4.51) ^b	NQC>AR

Notes. SES = socio-economic status, NQC = no questionnaire control arm, QC = questionnaire control arm, TPB = theory of planned behaviour arm, and AR = anticipated regret arm. Values with different superscripts are significantly different at $p < .05$ (cell proportions compared using z-tests with Bonferroni adjustments to the p-value). For the gender variable there was missing data for 65 participants, resulting in the total equalling 9,143 rather than 9,208.

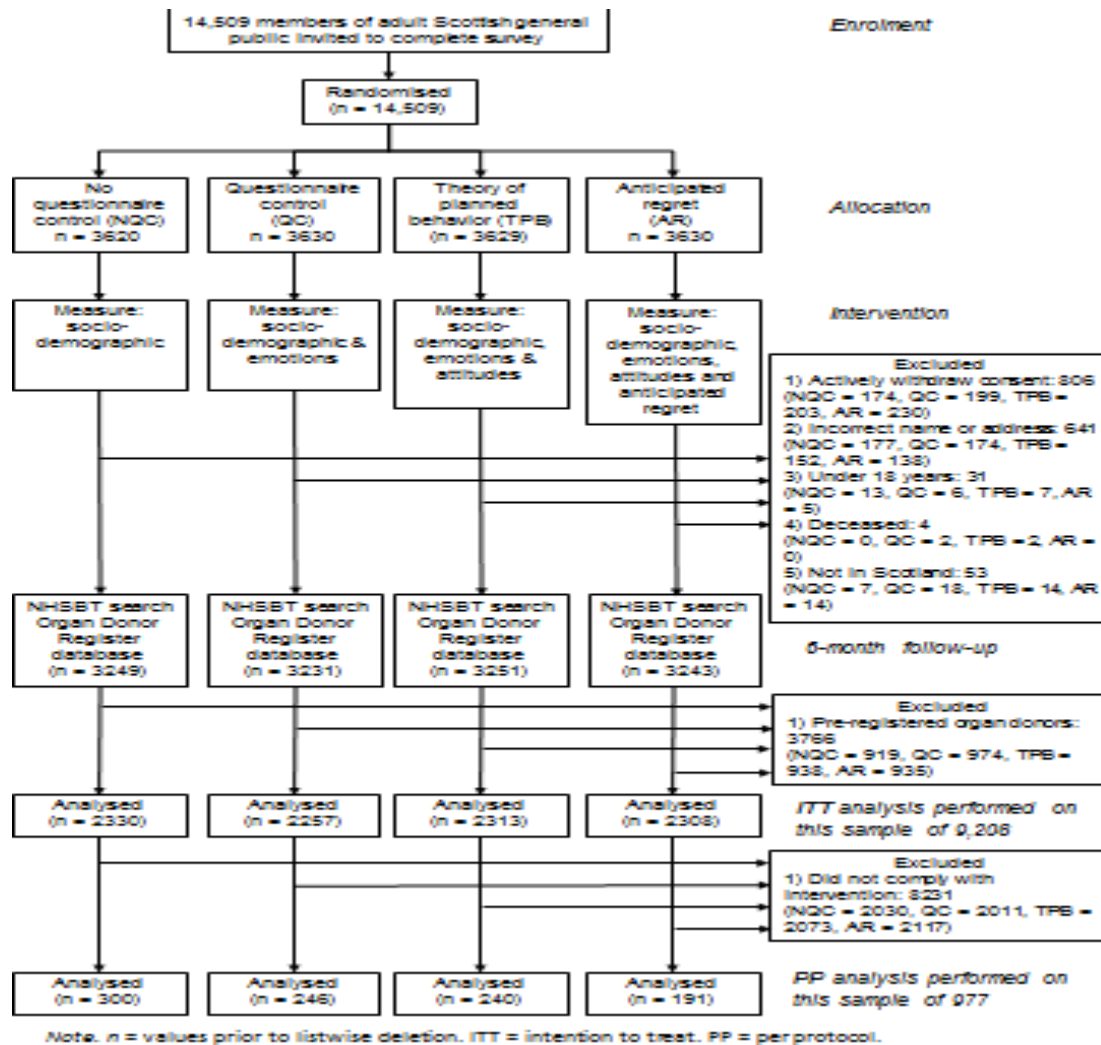
Table 2. Logistic regression comparing organ donor registration rates between the four experimental arms (ITT and PP analysis).

ITT (N = 9139)						PP (N = 961)				
Step 1		Step 2		Actual Power		Step 1		Step 2		Actual Power
B (SE)	OR (95% CI)	B (SE)	OR (95% CI)			B (SE)	OR (95% CI)	B (SE)	OR (95% CI)	
Gender										
Male ^a							1.00		1.00	
Female	0.38*** (0.10)	1.46 (1.21, 1.77)	0.38*** (0.10)	1.46 (1.21, 1.77)	.98	-0.04 (0.14)	0.97 (0.74, 1.27)	-0.04 (0.14)	0.96 (0.73, 1.27)	.06
Age	0.03*** (0.004)	1.03 (1.02, 1.04)	0.03*** (0.004)	1.03 (1.02, 1.04)	.09	-0.004 (0.01)	1.00 (0.98, 1.01)	-0.004 (0.01)	1.00 (0.98, 1.01)	.02
SES	0.05** (0.02)	1.05 (1.02, 1.09)	0.05** (0.02)	1.05 (1.02, 1.09)	.12	-0.05 [†] (0.03)	0.96 (0.91, 1.00)	-0.05 [†] (0.03)	0.95 (0.91, 1.00)	.09
Know recipient										
No ^a							1.00		1.00	
Yes						-0.02 (0.17)	0.98 (0.70, 1.37)	-0.01 (0.17)	0.99 (0.71, 1.39)	.07
Know donor										
No ^a							1.00		1.00	
Yes						-0.13 (0.22)	0.88 (0.57, 1.36)	-0.12 (0.22)	0.89 (0.58, 1.37)	.07

Know need					
No ^a				1.00	1.00
Yes			0.11 (0.24)	1.12 (0.71, 1.77)	1.12 (0.70, 1.77)
					.06
Donated blood					
No ^a				1.00	1.00
Yes			0.15 (0.14)	1.16 (0.89, 1.51)	1.16 (0.89, 1.51)
					.15
Arm					
NQC ^a					1.00
QC	-0.21 (0.13)	0.81 (0.63, 1.05)	.40	-0.36* (0.18)	0.70 (0.49, 0.99)
TPB	-0.20 (0.13)	0.82 (0.64, 1.05)	.35	-0.15 (0.18)	0.86 (0.61, 1.22)
AR	-0.38** (0.13)	0.69 (0.53, 0.89)	.83	-0.29 (0.19)	0.75 (0.51, 1.09)
					.50
					.14
					.32
Nagelkerke pseudo-R ²					
	0.03	0.03		0.01	0.01
Step χ^2					
	77.76***	8.29*		5.51	4.70
Model χ^2					
		86.05***			10.21

Notes. [†] = $p < .10$, * = $p < .05$, ** = $p < .01$, and *** = $p < .001$. ^a = Reference category. The mean level of anticipated regret for the compliant participants was 3.96 (SD = 1.68). ITT = intention to treat, PP = per protocol, SES = socio-economic status, NQC = no questionnaire control arm, QC = questionnaire control arm, TPB = theory of planned behaviour arm, AR = anticipated regret arm, know recipient = whether or not person knows someone who has received an organ, know donor = whether or no person knows someone who has donated an organ, know need = whether or not person knows someone who needs an organ, and donated blood = whether or not they have donated blood in the past.

Figure 1. Consort Diagram



Supplemental Materials

Returning the Questionnaire

Although we predominantly focused on the role of compliance, it is also important to assess the factors that predicted returning the questionnaire. This analysis was undertaken on all the eligible participants ($N = 9,208$). There was a significant association between condition and returning the questionnaire ($\chi^2(3) = 8.08, p = .044$). Return rates were lower in the AR arm ($n = 255, 11.05\%$) than the NQC ($n = 300, 12.88\%$), QC ($n = 310, 13.74\%$), and TPB arms ($n = 300, 12.97\%$). The standardised residuals indicated that the significant chi-squared value was due to the low number of questionnaire returned in the AR arm ($z = -2.17$). Return rate was also associated with gender ($\chi^2(1) = 53.88, p < .001$), with women being more likely to return the questionnaire ($n = 765, 14.88\%$) than men ($n = 390, 9.74\%$). People who returned the questionnaire were older ($M = 45.33, SD = 10.63$) than those who did not return the questionnaire ($M = 40.39, SD = 11.81; t(1610.00) = 14.60, p < .001, \text{Glass's } \Delta = 0.42$). People who returned the questionnaire were also higher in SES ($M = 5.75, SD = 2.74$) than those who did not ($M = 4.96, SD = 2.79; t(9202) = 9.07, p < .001, \text{Cohen's } d = .29$).

We conducted a logistic regression to determine which factors uniquely predicted returning the questionnaire. In this analysis the predictors were the demographics (age, gender, and SES) and arm. The outcome was returning the questionnaire. In this analysis ($N = 9,139$ after listwise deletion) returning the questionnaire was predicted by gender ($B = 0.49, p < .001, OR = 1.63$), age ($B = 0.04, p < .001, OR = 1.04$), and SES ($B = 0.09, p < .001, OR = 1.09$). Return rates for the NQC arm were not significantly different from the QC ($B = 0.09, p = .316, OR = 1.09$), TPB ($B = -0.01, p = .919, OR = 0.99$), or AR arm ($B = -0.17, p = .066, OR = 0.84$). These results reflect the fact that the demographics (but not arm) uniquely predicted whether or not the participant returned the questionnaire.

Theory of Planned Behaviour Associations

The correlations between the affective attitudes, intention, and organ donor registration were examined (see Table S1). This analysis could only be conducted on participants who had completed these items on the questionnaire, and therefore the participant must have returned the question and completed these items to be included into the analysis. Bodily integrity, medical mistrust, the ick factor, and jinx negatively predicted intention and behaviour. Perceived benefit positively predicted intention and behaviour.

The aim was to test whether any differences between arms was due to intention and/or the affective attitudes. Due to the nature of the questionnaire, these variables were not measured in the NQC arm. Therefore, it was not possible to test whether these variables mediated the differences between the NQC and the other 3 arms. As mentioned above, there was no difference in the number of registered organ donors between the QC, TPB, and AR arms. This analysis could only be performed on people who had returned the questionnaire because they had completed the appropriate items. Arm did not have a significant effect on the affective attitudes or intention (Table S2). Analysis – using Process (Hayes, 2013) indicated there were no significant indirect effect of arm on registration via intention or the affective attitudes (i.e. confidence intervals included zero).

Reference

Hayes, A. F. (2013). Introduction to mediation, moderation and conditional processes analysis: A regression-based approach. New York: Guilford Press.

Table S1. Correlation coefficients between affective attitudes, intention, and organ donor registration.

	M (SD)	1	2	3	4	5	6
1) Bodily integrity	2.35 (1.51)	-					
2) Medical mistrust	2.32 (1.27)	.36*** n = 864	-				
3) Ick factor	1.93 (1.25)	.57*** n = 864	.39*** n = 864	-			
4) Jinx	1.80 (1.15)	.43*** n = 863	.39*** n = 863	.45*** n = 863	-		
5) Perceived benefit	5.20 (1.24)	-.31*** n = 864	-.09** n = 864	-.32*** n = 864	-.05 n = 863	-	
6) Intention	4.54 (2.00)	-.43*** n = 699	-.26*** n = 699	-.41*** n = 699	-.15*** n = 698	.30*** n = 699	-
7) Organ donor registration ^a	-	-.26*** n = 864	-.15*** n = 864	-.27*** n = 864	-.10** n = 863	.11** n = 864	.61*** n = 700

* = $p < .05$, ** = $p < .01$, *** = $p < .001$. ^a = reference category. This was a point-biserial

correlation. Note: ns differ from the main analyses due to incomplete questionnaire data.

Table S2. Effect of arm on affective attitudes and intention.

	N in analysis	QC M (SD)	TPB M (SD)	AR M (SD)	Significance
Bodily Integrity	864	2.36 (1.49)	2.40 (1.51)	2.27 (1.54)	$F(2, 861) = 0.48, p = .618, \eta_p^2 < .01$
Medical Mistrust	864	2.22 (1.19)	2.41 (1.28)	2.34 (1.33)	$F(2, 861) = 1.65, p = .192, \eta_p^2 < .01$
Ick Factor	864	1.96 (1.26)	1.91 (1.23)	1.93 (1.27)	$F(2, 861) = 0.14, p = .871, \eta_p^2 < .01$
Jinx	863	1.79 (1.12)	1.79 (1.11)	1.81 (1.23)	$F(2, 860) = 0.04, p = .959, \eta_p^2 < .01$
Perceived Benefit	864	5.19 (1.19)	5.23 (1.21)	5.18 (1.33)	$F(2, 861) = 0.13, p = .877, \eta_p^2 < .01$
Intention	700	4.47 (1.99)	4.70 (1.99)	4.44 (2.05)	$F(2, 697) = 1.14, p = .320, \eta_p^2 < .01$

Note. QC = questionnaire control arm, TPB = theory of planned behaviour arm, and AR = anticipated regret arm. Note: ns differ from the main analyses due to incomplete questionnaire data.